

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

Jackie Cole, et al.	)	
	)	
Plaintiffs,	)	
	)	CIVIL ACTION
v.	)	
	)	NO. 04-11086 GAO
Indevus Pharmaceuticals, Inc., F/K/A Interneuron	)	
Pharmaceuticals, Inc.; Wyeth, Inc., F/K/A American Home	)	
Products Corporation; Wyeth Pharmaceuticals, Inc. F/K/A	)	
Wyeth-Ayerst Pharmaceuticals, Inc., A Division Of American	)	
Home Products Corporation; and Boehringer Ingelheim	)	
Pharmaceuticals, Inc.,	)	
	)	
Defendants.	)	
	)	

**WYETH DEFENDANTS' ANSWER TO PLAINTIFFS' AMENDED COMPLAINT**

Defendants Wyeth<sup>1</sup> (formerly known as American Home Products Corporation (“AHPC”)) (incorrectly denominated in Plaintiffs’ Complaint as “Wyeth Inc., F/K/A American Home Products Corporation”)) and Wyeth Pharmaceuticals Inc. (incorrectly denominated in Plaintiffs’ Complaint as Wyeth Pharmaceuticals, Inc. F/K/A Wyeth-Ayerst Pharmaceuticals, Inc., a Division of American Home Products Corporation”) (collectively, “Answering Defendants”), answer the allegations in Plaintiffs’ Amended Complaint as follows:

1. Answering Defendants admit that from approximately December 1989 to September 15, 1997, AHPC, through its Wyeth-Ayerst Laboratories Division (“WALD”), labeled, marketed, distributed, and sold Pondimin for use in accordance with its Food and Drug Administration (“FDA”)-approved prescribing information and all warnings, precautions, and contraindications stated therein. Answering Defendants further admit that from June 1996 to

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<sup>1</sup> On March 11, 2002, American Home Products Corporation changed its name to Wyeth. On March 22, 2002, Wyeth-Ayerst Pharmaceuticals Inc. changed its name to Wyeth Pharmaceuticals Inc.

September 15, 1997, AHPC, through WALD, labeled, marketed, distributed, promoted to licensed health care providers, and sold, Redux for use in accordance with the FDA-approved prescribing information and all warnings, precautions, and contraindications stated therein. Answering Defendants deny the remaining allegations in paragraph 1 of the Complaint and demand strict proof thereof.

2. Answering Defendants are without knowledge or information sufficient to form a belief as to Plaintiffs' residency, health or prescription histories and therefore deny said allegations and demand strict proof thereof. Answering Defendants are without knowledge or information sufficient to form a belief as to the remainder of the allegations in paragraph 2 and its subparts (a) through (j) and therefore deny those allegations and demand strict proof thereof.

3. Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3 and therefore deny those allegations and demand strict proof thereof.

4. Answering Defendants are without knowledge or information sufficient at this time to form a belief as to whether Plaintiffs qualify under the Nationwide Class Action Settlement Agreement with American Home Products Corporation (the "Settlement Agreement") to exercise Intermediate and/or Back-End Opt-Out rights under that Agreement, and therefore deny said allegations and demand strict proof thereof. Answering Defendants are without knowledge or information sufficient to form a belief as to the remainder of the allegations in paragraph 4, and therefore deny said allegations and demand strict proof thereof.

5. Answering Defendants deny each and every allegation in paragraph 5 of the Complaint and demand strict proof thereof.

6. Answering Defendants deny each and every allegation in paragraph 6 of the Complaint and demand strict proof thereof.

7. Answering Defendants deny each and every allegation in paragraph 7 of the Complaint and demand strict proof thereof.

8. Answering Defendants deny each and every allegation in paragraph 8 of the Complaint and demand strict proof thereof.

9. Answering Defendants deny that the drugs that are the subject of this Complaint are defective or unreasonably dangerous. Answering Defendants deny each and every allegation in paragraph 9 of the Complaint and demand strict proof thereof.

10. Paragraph 10 of the Complaint sets forth legal conclusions to which no response is required. To the extent a response is deemed necessary, Answering Defendants admit only to those duties imposed by law. Answering Defendants deny the remaining allegations in paragraph 10 of the Complaint and demand strict proof thereof.

11. Answering Defendants deny each and every allegation in paragraph 11 of the Complaint and demand strict proof thereof.

12. To the extent the allegations of paragraph 12 of the Complaint are directed at Answering Defendants, Answering Defendants deny said allegations and demand strict proof thereof. To the extent the allegations of paragraph 12 of the Complaint are directed at Indevus only, Answering Defendants, on information and belief, admit that Indevus is incorporated in the State of Delaware and has its principal place of business in Massachusetts. Answering Defendants are without knowledge or information sufficient to form a belief concerning the remaining allegations of paragraph 12, and therefore deny said allegations and demand strict proof thereof.

13. Answering Defendants admit that Wyeth is incorporated under the laws of Delaware with its principal place of business in New Jersey. Answering Defendants further admit that from approximately December 1989 to September 15, 1997, AHPC, through WALD,

labeled, marketed, distributed, and sold Pondimin, in interstate commerce, including in the State of Massachusetts, for use in accordance with the FDA-approved prescribing information and all warnings, precautions, and contraindications stated therein. Answering Defendants further admit that from June 1996 to September 15, 1997, AHPC, through WALD, labeled, marketed, distributed, promoted to licensed health care providers, and sold, Redux, in interstate commerce, including in the State of Massachusetts, for use in accordance with the FDA-approved prescribing information and all warnings, precautions, and contraindications stated therein. Answering Defendants further admit that prior to September 15, 1997, A.H. Robins Company, Inc. (“A.H. Robins”) manufactured, labeled, distributed and sold Pondimin for use in accordance with the FDA-approved prescribing information and all warnings, precautions, and contraindications stated therein, and that Wyeth acquired A.H. Robins in 1989. Answering Defendants further admit that prior to its acquisition by AHPC in 1989, A.H. Robins had its principal place of business in Virginia. Answering Defendants further admit that in late 1994, American Cyanamid Company (“Cyanamid”) entered into a “Patent and Know-How Sublicense and Supply Agreement” with Interneuron Pharmaceuticals, Inc. (“Interneuron”), and that prior to this time, Interneuron had entered into a sublicense and supply agreement with Les Laboratoires Servier (“Servier”). Answering Defendants deny each and every other allegation in paragraph 13 of the Complaint and demand strict proof thereof.

14. Answering Defendants admit that Wyeth Pharmaceuticals was formerly known as WALD, is an unincorporated division of Wyeth, and is not separately amenable to suit.<sup>2</sup> Answering Defendants admit that Wyeth is incorporated under the laws of Delaware. Answering Defendants further admit that from approximately December 1989 to September 15, 1997,

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<sup>2</sup> Answering Defendants note that Plaintiffs have named only Wyeth and Wyeth Pharmaceuticals Inc., as Wyeth defendants, yet refer to Wyeth Pharmaceuticals as a defendant in Paragraph 14 of the Complaint.

AHPC, through WALD, labeled, marketed, distributed, and sold Pondimin, in interstate commerce, including in the State of Massachusetts, for use in accordance with the FDA-approved prescribing information and all warnings, precautions, and contraindications stated therein. Answering Defendants further admit that from June 1996 to September 15, 1997, AHPC, through WALD, labeled, marketed, distributed, promoted to licensed health care providers, and sold, Redux, in interstate commerce, including in the State of Massachusetts, for use in accordance with the FDA-approved prescribing information and all warnings, precautions, and contraindications stated therein. Answering Defendants further admit that prior to September 15, 1997,

A.H. Robins manufactured, labeled, distributed and sold Pondimin for use in accordance with the FDA-approved prescribing information and all warnings, precautions, and contraindications stated therein, and that Wyeth acquired A.H. Robins in 1989. Answering Defendants further admit that prior to its acquisition by AHPC in 1989, A.H. Robins had its principal place of business in Virginia. Answering Defendants further admit that in late 1994, Cyanamid entered into a “Patent and Know-How Sublicense and Supply Agreement” with Interneuron, and that prior to this time, Interneuron had entered into a sublicense and supply agreement with Servier. Answering Defendants deny each and every other allegation in paragraph 14 of the Complaint and demand strict proof thereof.

15. To the extent the allegations of paragraph 15 of the Complaint are directed at Answering Defendants, Answering Defendants admit that Boehringer entered into a Contract Manufacturing Agreement with Interneuron on November 21, 1995. That contract speaks for itself and Answering Defendants deny any attempt to characterize the contents of that contract. Answering Defendants deny the remaining allegations of Paragraph 15 to the extent those allegations are directed at Answering Defendants and demand strict proof thereof. To the extent

the allegations of paragraph 15 of the Complaint are directed at Boehringer only, Answering Defendants are without knowledge or information sufficient to form a belief concerning said allegations, and therefore deny said allegations and demand strict proof thereof. The final sentence of Paragraph 15 is a descriptive statement to which no response is required.

16. To the extent the allegations of paragraph 16 of the Complaint are directed at Answering Defendants, Answering Defendants deny said allegations and demand strict proof thereof. Answering Defendants are without knowledge or information sufficient to form a belief concerning said allegations, and therefore deny said allegations and demand strict proof thereof.

17. Answering Defendants admit that fenfluramine and dexfenfluramine have anorectic effects, as more fully described in their respective FDA-approved prescribing information. Answering Defendants further admit that serotonin is a neurotransmitter. Answering Defendants deny the remaining allegations of paragraph 17 and demand strict proof thereof.

18. Answering Defendants admit that on May 30, 1963, A.H. Robins obtained a license from Science Union & Co., an affiliate of Servier. Answering Defendants further admit that Wyeth acquired A.H. Robins in 1989. Answering Defendants deny the remaining allegations of paragraph 18 of the Complaint and demand strict proof thereof.

19. Answering Defendants admit, upon information and belief, that Servier was issued a patent for the drug product fenfluramine hydrochloride on August 3, 1965, and that prior to February 7, 1990, Servier held the patent rights to the drug product dexfenfluramine hydrochloride. Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 19 and therefore deny those allegations and demand strict proof thereof.

20. To the extent the allegations of paragraph 20 are directed at Answering Defendants, Answering Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations and therefore deny those allegations and demand strict proof thereof.

21. Answering Defendants admit, upon information and belief, that Servier granted Interneuron a license in the United States with respect to dexfenfluramine. Answering Defendants further admit that Cyanamid obtained a sublicense from Interneuron with respect to dexfenfluramine and that, upon information and belief, there was a “Patent and Know-How Sublicense and Supply Agreement” between Cyanamid and Interneuron with respect to dexfenfluramine. Answering Defendants further admit that in late December 1994, AHPC acquired Cyanamid. Answering Defendants further admit that through WALD, AHPC intended to market dexfenfluramine hydrochloride upon FDA approval. Answering Defendants deny the remaining allegations in paragraph 21 of the Complaint and demand strict proof thereof.

22. Answering Defendants admit that A.H. Robins manufactured, labeled, distributed and sold Pondimin brand of fenfluramine for use in accordance with the FDA-approved prescribing information and all warnings, precautions and contraindications stated therein. Answering Defendants deny the remaining allegations of paragraph 22 of the Complaint and demand strict proof thereof.

23. Answering Defendants affirmatively state that any referenced research results speak for themselves and deny any attempt to characterize those results. Answering Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 23 of the Complaint and therefore deny the same and demand strict proof thereof.

24. Answering Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 24 of the Complaint and therefore deny the same and demand strict proof thereof.

25. Answering Defendants affirmatively state that the referenced articles speak for themselves and deny any attempt to characterize the content of those articles. Answering Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 25 of the Complaint, and therefore deny the same and demand strict proof thereof.

26. Answering Defendants affirmatively state that the referenced publications speak for themselves and deny any attempt to characterize those documents. Answering Defendants deny the remaining allegations in paragraph 26 of the Complaint and demand strict proof thereof.

27. Answering Defendants admit that Servier sold dexfenfluramine in Europe. Answering Defendants are without knowledge or information sufficient to form a belief as to the remaining allegations in paragraph 27, and therefore deny said allegations and demand strict proof thereof.

28. Answering Defendants admit that MIT and Dr. Wurtman developed dexfenfluramine. Answering Defendants lack sufficient knowledge or information to form a belief as to the truth of the remaining allegations in paragraph 28 of the Complaint and therefore deny said allegations and demand strict proof thereof.

29. Answering Defendants admit, upon information and belief, that Servier granted Interneuron a license in the United States with respect to dexfenfluramine. Answering Defendants lack sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 29 and therefore deny said allegations and demand strict proof thereof.



30. Answering Defendants deny each and every allegation in paragraph 30 of the Complaint and demand strict proof thereof.

31. Answering Defendants deny each and every allegation in paragraph 31 of the Complaint and demand strict proof thereof.

32. Answering Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 32 and therefore deny said allegations and demand strict proof thereof.

33. Answering Defendants admit, upon information and belief, that Interneuron obtained approval for Redux from the FDA in 1996. Answering Defendants lack sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 33 and therefore deny said allegations and demand strict proof thereof.

34. Answering Defendants affirmatively state that the referenced articles speak for themselves and deny any attempt to characterize the content of those articles. Answering Defendants deny the remaining allegations in paragraph 34 of the Complaint and demand strict proof thereof.

35. Answering Defendants admit, upon information and belief, that Cyanamid obtained a sublicense from Interneuron with respect to dexfenfluramine and that there was a “Patent and Know-How Sublicense and Supply Agreement” between Cyanamid and Interneuron with respect to dexfenfluramine. Answering Defendants further admit that in late December 1994, AHPC acquired Cyanamid. Answering Defendants deny the remaining allegations of paragraph 35 of the Complaint and demand strict proof thereof.

36. To the extent the allegations in paragraph 36 rely on documents or witness testimony, the documents and testimony speak for themselves, and Answering Defendants deny

any attempt to characterize their content. Answering Defendants deny the remaining allegations in paragraph 36 of the Complaint and demand strict proof thereof.

37. Answering Defendants affirmatively state that the referenced article and Pondimin labeling speak for themselves and deny any attempt to characterize the content of those documents. Answering Defendants deny the remaining allegations in paragraph 37 of the Complaint and demand strict proof thereof.

38. Answering Defendants admit, on information and belief, that Interneuron filed an NDA with the FDA for the approval of Redux. Answering Defendants affirmatively state that the contents of that NDA speak for themselves and deny any attempt to characterize the NDA. Answering Defendants deny the remaining allegations in paragraph 38 of the Complaint and demand strict proof thereof.

39. Answering Defendants deny each and every allegation in paragraph 39 of the Complaint including its subparts (a) through (c), and demand strict proof thereof.

40. Answering Defendants deny each and every allegation in paragraph 40 of the Complaint and demand strict proof thereof.

41. Answering Defendants affirmatively state that the referenced articles speak for themselves and deny any attempt to characterize the content of those documents. Answering Defendants deny the remaining allegations in paragraph 41 of the Complaint and demand strict proof thereof.

42. Answering Defendants deny each and every allegation in paragraph 42 of the Complaint and demand strict proof thereof.

43. Answering Defendants affirmatively state that the referenced documents speak for themselves and deny any attempt to characterize the content of those documents. Answering

Defendants deny the remaining allegations in paragraph 43 of the Complaint and demand strict proof thereof.

44. Answering Defendants deny each and every allegation in paragraph 44 of the Complaint and demand strict proof thereof.

45. Answering Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 45 and therefore deny said allegations and demand strict proof thereof.

46. Answering Defendants admit that Amy Myers wrote a memo to Fred Wilson dated June 23, 1994. That memo speaks for itself and Answering Defendants deny any attempt to characterize the contents of that memo. Answering Defendants deny the remaining allegations in paragraph 46 of the Complaint and demand strict proof thereof.

47. Answering Defendants admit, upon information and belief, that Cyanamid obtained a sublicense from Interneuron with respect to dexfenfluramine and that there was a “Patent and Know-How Sublicense and Supply Agreement” between Cyanamid and Interneuron with respect to dexfenfluramine. Answering Defendants further admit that in late December 1994, AHPC acquired Cyanamid. Answering Defendants deny the remaining allegations of paragraph 47 of the Complaint and demand strict proof thereof.

48. Answering Defendants admit that AHPC acquired Cyanamid in late December 1994. Answering Defendants deny the remaining allegations of paragraph 48 of the Complaint and demand strict proof thereof.

49. Answering Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 49 and therefore deny said allegations and demand strict proof thereof.

50. Answering Defendants deny each and every allegation in paragraph 50 of the Complaint and demand strict proof thereof.

51. Answering Defendants affirmatively state that the referenced reports speak for themselves and deny any attempt to characterize the content of those documents. Answering Defendants deny the remaining allegations in paragraph 51 of the Complaint and demand strict proof thereof.

52. Answering Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 52 and therefore deny said allegations and demand strict proof thereof.

53. To the extent the allegations of paragraph 53 rely on referenced documents, those documents speak for themselves and Answering Defendants deny any attempt to characterize the content of those documents. Answering Defendants deny the remaining allegations in paragraph 53 of the Complaint and demand strict proof thereof.

54. Answering Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 54 and therefore deny said allegations and demand strict proof thereof.

55. Answering Defendants affirmatively state that the referenced media reports and articles speak for themselves and deny any attempt to characterize the content of those documents. Answering Defendants deny the remaining allegations in paragraph 55 of the Complaint and demand strict proof thereof.

56. Answering Defendants affirmatively state that the referenced documents speak for themselves and deny any attempt to characterize the content of those documents. Answering Defendants deny the remaining allegations in paragraph 56 of the Complaint and demand strict proof thereof.

57. Answering Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 57 and therefore deny said allegations and demand strict proof thereof.

58. Answering Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 58 and therefore deny said allegations and demand strict proof thereof.

59. Answering Defendants affirmatively state that the referenced documents speak for themselves and deny any attempt to characterize the content of those documents. Answering Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 59 and therefore deny said allegations and demand strict proof thereof.

60. Answering Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 60 and therefore deny said allegations and demand strict proof thereof.

61. Answering Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 61 and therefore deny said allegations and demand strict proof thereof.

62. Answering Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 62 and therefore deny said allegations and demand strict proof thereof.

63. Answering Defendants admit that Boehringer entered into a Contract Manufacturing Agreement with Interneuron on November 21, 1995. That contract speaks for itself and Answering Defendants deny any attempt to characterize the contents of that contract. Answering Defendants lack sufficient knowledge or information to form a belief as to the truth

of the remaining allegations of paragraph 63 and therefore deny said allegations and demand strict proof thereof.

64. Answering Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 64 and therefore deny said allegations and demand strict proof thereof.

65. Answering Defendants admit the allegations of paragraph 65 of the Complaint.

66. Answering Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 66 and therefore deny said allegations and demand strict proof thereof.

67. Answering Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 67 and therefore deny said allegations and demand strict proof thereof.

68. Answering Defendants affirmatively state that the referenced document speaks for itself and deny any attempt to characterize the content of that document. Answering Defendants deny the remaining allegations of paragraph 68 and demand strict proof thereof.

69. Answering Defendants affirmatively state that the referenced documents speak for themselves and deny any attempt to characterize the content of those documents. Answering Defendants deny the remaining allegations of paragraph 69 of the Complaint and demand strict proof thereof.

70. Answering Defendants affirmatively state that the referenced documents speak for themselves and deny any attempt to characterize the content of those documents. Answering Defendants deny the remaining allegations of paragraph 70 of the Complaint and demand strict proof thereof.

71. Answering Defendants deny each and every allegation of paragraph 71 of the Complaint and demand strict proof thereof.

72. Answering Defendants deny each and every allegation of paragraph 72 of the Complaint and demand strict proof thereof.

73. Answering Defendants deny each and every allegation of paragraph 73 of the Complaint and demand strict proof thereof.

74. Answering Defendants affirmatively state that the referenced documents speak for themselves and deny any attempt to characterize the content of those documents. Answering Defendants deny the remaining allegations of paragraph 74 of the Complaint, including its subparts (a) through (g), and demand strict proof thereof.

75. Answering Defendants admit that Dr. B. Taylor Thompson analyzed 32 pulmonary hypertension cases. Answering Defendants affirmatively state that the referenced analysis speaks for itself and deny any attempt to characterize the content of that analysis. Answering Defendants deny the remaining allegations of paragraph 75 of the Complaint and demand strict proof thereof.

76. Answering Defendants deny each and every allegation of paragraph 76 of the Complaint and demand strict proof thereof.

77. Answering Defendants admit that Interneuron and Wyeth entered into a co-marketing agreement under which Interneuron and WALD jointly promoted Redux to licensed health care providers. Answering Defendants deny the remaining allegations of paragraph 77 and demand strict proof thereof.

78. Answering Defendants affirmatively state that the referenced document speaks for itself and deny any attempt to characterize the content of that document. Answering Defendants

deny the remaining allegations of paragraph 78 of the Complaint and demand strict proof thereof.

79. Answering Defendants affirmatively state that the referenced document speaks for itself and deny any attempt to characterize the content of that document. Answering Defendants deny the remaining allegations of paragraph 79 of the Complaint and demand strict proof thereof.

80. Answering Defendants deny each and every allegation of paragraph 80 of the Complaint and demand strict proof thereof.

81. Answering Defendants admit that on or about July 8, 1997, the Mayo Clinic issued a press release discussing diet medications. Answering Defendants affirmatively state that the 1997 press release speaks for itself, and deny any attempt to characterize the contents of that press release. Answering Defendants deny the remaining allegations of paragraph 81 of the Complaint and demand strict proof thereof.

82. Answering Defendants affirmatively state that the referenced documents speak for themselves and deny any attempt to characterize the content of those documents. Answering Defendants deny the remaining allegations of paragraph 82 of the Complaint and demand strict proof thereof.

83. Answering Defendants admit that Wyeth learned of information during meetings with representatives of the Mayo Clinic and the MeritCare Medical Center. Answering Defendants deny the remaining allegations of paragraph 83 of the Complaint and demand strict proof thereof.

84. Answering Defendants admit that the FDA issued a Public Health Advisory on July 8, 1997. Answering Defendants affirmatively state that the Public Health Advisory speaks for itself and deny any attempt to characterize the content of that document. Answering



Defendants deny the remaining allegations of paragraph 84 of the Complaint and demand strict proof thereof.

85. Answering Defendants admit that AHPC voluntarily withdrew Pondimin and Redux from the market on September 15, 1997. Answering Defendants affirmatively state that the referenced data speaks for itself and deny any attempt to characterize the content of that data. Answering Defendants deny the remaining allegations of paragraph 85 of the Complaint and demand strict proof thereof.

86. Answering Defendants affirmatively state that the referenced article speaks for itself and deny any attempt to characterize that article. Answering Defendants deny the remaining allegations of paragraph 86 of the Complaint and demand strict proof thereof.

87. Answering Defendants affirmatively state that the referenced article speaks for itself and deny any attempt to characterize the content of that article. Answering Defendants deny the remaining allegations of paragraph 87 of the Complaint and demand strict proof thereof.

88. Answering Defendants affirmatively state that the referenced document speaks for itself and deny any attempt to characterize that document. Answering Defendants deny the remaining allegations of paragraph 88 of the Complaint and demand strict proof thereof.

#### **General Allegations**

89. Answering Defendants deny each and every allegation of paragraph 89 of the Complaint and demand strict proof thereof.

90. Answering Defendants deny each and every allegation of paragraph 90 of the Complaint and demand strict proof thereof.

91. Answering Defendants deny each and every allegation of paragraph 91 of the Complaint and demand strict proof thereof.

92. Answering Defendants deny each and every allegation of paragraph 92 of the Complaint and demand strict proof thereof.

93. Answering Defendants deny each and every allegation of paragraph 93 of the Complaint and demand strict proof thereof.

94. Answering Defendants deny each and every allegation of paragraph 94 of the Complaint and demand strict proof thereof.

95. Answering Defendants deny each and every allegation of paragraph 95 of the Complaint and demand strict proof thereof.

96. Answering Defendants deny each and every allegation of paragraph 96 of the Complaint and demand strict proof thereof.

97. Answering Defendants deny each and every allegation of paragraph 97 of the Complaint and demand strict proof thereof.

98. Answering Defendants deny each and every allegation of paragraph 98 of the Complaint and demand strict proof thereof.

99. Answering Defendants deny each and every allegation of paragraph 99 of the Complaint and demand strict proof thereof.

100. Answering Defendants deny each and every allegation of paragraph 100 of the Complaint and demand strict proof thereof.

101. Answering Defendants deny each and every allegation of paragraph 101 of the Complaint and demand strict proof thereof.

102. Answering Defendants deny each and every allegation of paragraph 102 of the Complaint and demand strict proof thereof.

103. Answering Defendants deny each and every allegation of paragraph 103 of the Complaint and demand strict proof thereof.

104. Answering Defendants deny each and every allegation of paragraph 104 of the Complaint, including its subparts (a) through (d), and demand strict proof thereof.

105. Answering Defendants deny each and every allegation of paragraph 105 of the Complaint and demand strict proof thereof.

106. Answering Defendants deny each and every allegation of paragraph 106 of the Complaint and demand strict proof thereof.

107. Answering Defendants deny each and every allegation of paragraph 107 of the Complaint and demand strict proof thereof.

108. Paragraph 108 sets forth a legal conclusion to which no response is required. To the extent a response is deemed necessary, Answering Defendants admit only to those duties imposed by law. Answering Defendants deny the remaining allegations of paragraph 108 of the Complaint and demand strict proof thereof.

109. Answering Defendants deny each and every allegation of paragraph 109 of the Complaint and demand strict proof thereof.

110. Answering Defendants deny making any fraudulent misrepresentations. Answering Defendants deny each and every allegation of paragraph 110 of the Complaint and demand strict proof thereof.

111. Answering Defendants deny each and every allegation of paragraph 111 of the Complaint and demand strict proof thereof.

112. Answering Defendants deny each and every allegation of paragraph 112 of the Complaint and demand strict proof thereof.

113. Answering Defendants deny each and every allegation of paragraph 113 of the Complaint, including its subparts (a) through (h), and demand strict proof thereof.

114. Answering Defendants admit that Pondimin and Redux were intended to reach users without a substantial change in the condition in which they were sold. Answering Defendants are without knowledge or information sufficient to form a belief as to whether the subject pharmaceuticals actually reached prescribing physicians or consumers, including Plaintiffs, without a substantial change in the condition in which they were sold. Answering Defendants therefore deny this allegation and demand strict proof thereof. Answering Defendants deny the remaining allegations of paragraph 114 of the Complaint and demand strict proof thereof.

115. Answering Defendants deny each and every allegation of paragraph 115 of the Complaint and demand strict proof thereof.

116. Answering Defendants admit employing sales representatives who provided information about Redux to licensed medical providers. Answering Defendants deny the remaining allegations of paragraph 116 of the Complaint and demand strict proof thereof.

117. Answering Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations regarding any medications taken by Plaintiffs or any warnings they received regarding those medications and therefore deny those allegations and demand strict proof thereof. Answering Defendants deny the remaining allegations of paragraph 117 and demand strict proof thereof.

**Count I**  
**Breach of Warranty**  
**Defective Design**

118. Answering Defendants adopt by reference their responses to all of the foregoing allegations as though fully set forth herein.

119. Answering Defendants admit marketing and promoting the subject pharmaceuticals only to the extent described above in their responses to paragraphs 13 and 14 of

the Complaint. Answering Defendants deny the remaining allegations of paragraph 119 and demand strict proof thereof.

120. Answering Defendants admit that Pondimin and Redux were intended to reach users without a substantial change in the condition in which they were sold. Answering Defendants are without knowledge or information sufficient to form a belief as to whether the subject pharmaceuticals actually reached prescribing physicians or consumers, including Plaintiffs, without a substantial change in the condition in which they were sold. Answering Defendants therefore deny this allegation and demand strict proof thereof. Answering Defendants deny the remaining allegations of paragraph 120 and demand strict proof thereof.

121. Answering Defendants deny each and every allegation of paragraph 121 of the Complaint, including its subparts (a) through (e), and demand strict proof thereof.

122. Answering Defendants deny each and every allegation of paragraph 122 of the Complaint and demand strict proof thereof.

123. Answering Defendants deny each and every allegation of paragraph 123 of the Complaint and demand strict proof thereof.

With respect to the “WHEREFORE” paragraph immediately following paragraph 123, Answering Defendants admit that Plaintiffs seek the relief requested but deny that Plaintiffs are entitled to any relief whatsoever.

**Count II**  
**Breach of Warranty**  
**Failure to Warn**

124. Answering Defendants adopt by reference their responses to all of the foregoing allegations as though fully set forth herein.

125. Answering Defendants deny each and every allegation in paragraph 125 of the Complaint and demand strict proof thereof.

126. Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 126 of the Complaint, and therefore deny said allegations and demand strict proof thereof.

127. Answering Defendants deny the allegation in paragraph 127 of the Complaint that Pondimin and/or Redux were defective. Answering Defendants are without knowledge or information as to whether the prescribing physicians could have discovered a defect, if any, in the subject pharmaceuticals and therefore deny said allegation and demand strict proof thereof. Answering Defendants deny the remaining allegations of paragraph 127 and demand strict proof thereof.

128. Paragraph 128 of the Complaint sets forth a legal conclusion to which no response is required. To the extent a response is deemed necessary, Answering Defendants admit only to those duties imposed by law. Answering Defendants deny the remaining allegations in paragraph 128 of the Complaint and demand strict proof thereof.

129. Paragraph 129 is vague and confusing. To the extent any allegations in paragraph 129 are directed at Answering Defendants, Answering Defendants deny the allegations in paragraph 129 of the Complaint and demand strict proof thereof.

130. Answering Defendants deny each and every allegation in paragraph 130 of the Complaint and demand strict proof thereof.

131. Answering Defendants deny each and every allegation in paragraph 131 of the Complaint and demand strict proof thereof.

132. Paragraph 132 of the Complaint sets forth a legal conclusion to which no response is required. To the extent a response is deemed necessary, Answering Defendants admit only to those duties imposed by law. Answering Defendants deny the remaining allegations in paragraph 132 of the Complaint and demand strict proof thereof.

133. Paragraph 133 of the Complaint sets forth a legal conclusion to which no response is required. To the extent a response is deemed necessary, Answering Defendants admit only to those duties imposed by law. Answering Defendants deny the remaining allegations in paragraph 133 of the Complaint and demand strict proof thereof.

With respect to the “WHEREFORE” paragraph immediately following paragraph 133, Answering Defendants admit that Plaintiffs seek the relief requested but deny that Plaintiffs are entitled to any such relief.

**Count III**  
**Negligence**

134. Answering Defendants adopt by reference their responses to all of the foregoing allegations as though fully set forth herein.

135. Answering Defendants deny each and every allegation in paragraph 135 of the Complaint and demand strict proof thereof.

136. Paragraph 136 of the Complaint sets forth a legal conclusion to which no response is required. To the extent a response is deemed necessary, Answering Defendants admit only to those duties imposed by law. Answering Defendants deny the remaining allegations of paragraph 136 and demand strict proof thereof.

137. Answering Defendants deny each and every allegation in paragraph 137 of the Complaint, including subparagraphs (a) through (n), and demand strict proof thereof.

138. Answering Defendants deny each and every allegation in paragraph 138 of the Complaint and demand strict proof thereof.

139. Answering Defendants deny any negligent conduct. Answering Defendants lack sufficient knowledge or information to form a belief about what Plaintiffs’ physicians may or may not have done and therefore deny said allegations and demand strict proof thereof.

Answering Defendants deny the remaining allegations in paragraph 139 of the Complaint and demand strict proof thereof.

140. Answering Defendants deny each and every allegation in paragraph 140 of the Complaint and demand strict proof thereof.

With respect to the “WHEREFORE” paragraph immediately following paragraph 140, Answering Defendants admit that Plaintiffs seek the relief requested but deny that Plaintiffs are entitled to any such relief.

**Count IV**  
**Fraudulent Misrepresentation & Fraudulent Concealment**

141. Answering Defendants adopt by reference their responses to all of the foregoing allegations as though fully set forth herein.

142. Paragraph 142 of the Complaint sets forth a legal conclusion to which no response is required. To the extent a response is deemed necessary, Answering Defendants admit only to those duties imposed by law. Answering Defendants deny the remaining allegations in paragraph 142 of the Complaint and demand strict proof thereof.

143. Answering Defendants deny each and every allegation in paragraph 143 of the Complaint and demand strict proof thereof.

144. Answering Defendants deny each and every allegation in paragraph 144 of the Complaint and demand strict proof thereof.

145. Answering Defendants deny each and every allegation in paragraph 145 of the Complaint and demand strict proof thereof.

146. Answering Defendants deny making any fraudulent misrepresentations. Answering Defendants deny each and every other allegation in paragraph 146 of the Complaint, including its subparts (a) through (n), and demand strict proof thereof.



147. Answering Defendants deny making any false and/or misleading representations. Answering Defendants deny each and every other allegation in paragraph 147 of the Complaint and demand strict proof thereof.

148. Answering Defendants deny making any fraudulent misrepresentations. Answering Defendants deny each and every other allegation of paragraph 148 of the Complaint, and demand strict proof thereof.

149. Answering Defendants deny making any false and/or misleading representations. Answering Defendants deny each and every other allegation of paragraph 149 of the Complaint and demand strict proof thereof.

150. Answering Defendants deny making any false and/or misleading representations. Answering Defendants are without knowledge or information sufficient to form a belief concerning the remaining allegations of paragraph 150 of the Complaint, and therefore deny said allegations and demand strict proof thereof.

151. Answering Defendants deny making any false and/or misleading representations. Answering Defendants are without knowledge or information sufficient to form a belief concerning the remaining allegations of paragraph 151 of the Complaint, and therefore deny said allegations and demand strict proof thereof.

152. Paragraph 152 of the Complaint sets forth a legal conclusion to which no response is required. To the extent a response is deemed necessary, Answering Defendants admit only to those duties imposed by law. Answering Defendants deny the remaining allegations of paragraph 152 and demand strict proof thereof.

153. Answering Defendants deny making any misrepresentations. Answering Defendants deny each and every other allegation in paragraph 153 of the Complaint and demand strict proof thereof.

154. Answering Defendants deny making any misrepresentations and/or concealing any matter. Answering Defendants deny each and every other allegation in paragraph 154 of the Complaint and demand strict proof thereof.

155. Answering Defendants deny each and every allegation in paragraph 155 of the Complaint and demand strict proof thereof.

With respect to the “WHEREFORE” paragraph immediately following paragraph 155, Answering Defendants admit that Plaintiffs seek the relief requested but deny that Plaintiffs are entitled to any such relief.

**Count V**  
**Fraudulent Concealment**  
**(Against Defendants Interneuron Only)**

156. Answering Defendants adopt by reference their responses to all of the foregoing allegations as though fully set forth herein.

157. Paragraph 157 contains allegations that are not directed at Answering Defendants and therefore require no response from Answering Defendants. To the extent the allegations are directed at Answering Defendants, Answering Defendants deny those allegations and demand strict proof thereof.

158. Paragraph 158 contains allegations that are not directed at Answering Defendants and therefore require no response from Answering Defendants. To the extent the allegations are directed at Answering Defendants, Answering Defendants deny those allegations and demand strict proof thereof.

159. Paragraph 159 contains allegations that are not directed at Answering Defendants and therefore require no response from Answering Defendants. To the extent the allegations are directed at Answering Defendants, Answering Defendants deny those allegations and demand strict proof thereof.

160. Paragraph 160 contains allegations that are not directed at Answering Defendants and therefore require no response from Answering Defendants. To the extent the allegations are directed at Answering Defendants, Answering Defendants deny those allegations and demand strict proof thereof.

161. Paragraph 161 contains allegations that are not directed at Answering Defendants and therefore require no response from Answering Defendants. To the extent the allegations are directed at Answering Defendants, Answering Defendants deny those allegations and demand strict proof thereof.

162. Paragraph 162 contains allegations that are not directed at Answering Defendants and therefore require no response from Answering Defendants. To the extent the allegations are directed at Answering Defendants, Answering Defendants deny those allegations and demand strict proof thereof.

163. Paragraph 163 contains allegations that are not directed at Answering Defendants and therefore require no response from Answering Defendants. To the extent the allegations are directed at Answering Defendants, Answering Defendants deny those allegations and demand strict proof thereof.

164. Paragraph 164 contains allegations that are not directed at Answering Defendants and therefore require no response from Answering Defendants. To the extent the allegations are directed at Answering Defendants, Answering Defendants deny those allegations and demand strict proof thereof.

165. Paragraph 165 contains allegations that are not directed at Answering Defendants and therefore require no response from Answering Defendants. To the extent the allegations are directed at Answering Defendants, Answering Defendants deny those allegations and demand strict proof thereof.

166. Paragraph 166 contains allegations that are not directed at Answering Defendants and therefore require no response from Answering Defendants. To the extent the allegations are directed at Answering Defendants, Answering Defendants deny those allegations and demand strict proof thereof.

167. Paragraph 167 contains allegations that are not directed at Answering Defendants and therefore require no response from Answering Defendants. To the extent the allegations are directed at Answering Defendants, Answering Defendants deny those allegations and demand strict proof thereof.

168. Paragraph 168 contains allegations that are not directed at Answering Defendants and therefore require no response from Answering Defendants. To the extent the allegations are directed at Answering Defendants, Answering Defendants deny those allegations and demand strict proof thereof.

169. Paragraph 169 contains allegations that are not directed at Answering Defendants and therefore require no response from Answering Defendants. To the extent the allegations are directed at Answering Defendants, Answering Defendants deny those allegations and demand strict proof thereof.

170. Paragraph 170 contains allegations that are not directed at Answering Defendants and therefore require no response from Answering Defendants. To the extent the allegations are directed at Answering Defendants, Answering Defendants deny those allegations and demand strict proof thereof.

With respect to the “WHEREFORE” paragraph immediately following paragraph 170, Answering Defendants admit that Plaintiffs seek the relief requested but deny that Plaintiffs are entitled to any such relief.

**Count VI**  
**Unfair and Deceptive Trade Practices**  
**(Against Defendants Interneuron and Boehringer Only)**

171. Answering Defendants adopt by reference their responses to all of the foregoing allegations as though fully set forth herein.

172. Paragraph 172 contains allegations that are not directed at Answering Defendants and therefore require no response from Answering Defendants. To the extent the allegations are directed at Answering Defendants, Answering Defendants deny those allegations and demand strict proof thereof.

173. Paragraph 173 contains allegations that are not directed at Answering Defendants and therefore require no response from Answering Defendants. To the extent the allegations are directed at Answering Defendants, Answering Defendants deny those allegations and demand strict proof thereof.

174. Paragraph 174 contains allegations that are not directed at Answering Defendants and therefore require no response from Answering Defendants. To the extent the allegations are directed at Answering Defendants, Answering Defendants deny those allegations and demand strict proof thereof.

175. Paragraph 175 contains allegations that are not directed at Answering Defendants and therefore require no response from Answering Defendants. To the extent the allegations are directed at Answering Defendants, Answering Defendants deny those allegations and demand strict proof thereof.

176. Paragraph 176 contains allegations that are not directed at Answering Defendants and therefore require no response from Answering Defendants. To the extent the allegations are directed at Answering Defendants, Answering Defendants deny those allegations and demand strict proof thereof.

177. Paragraph 177 contains allegations that are not directed at Answering Defendants and therefore require no response from Answering Defendants. To the extent the allegations are directed at Answering Defendants, Answering Defendants deny those allegations and demand strict proof thereof.

178. Paragraph 178 contains allegations that are not directed at Answering Defendants and therefore require no response from Answering Defendants. To the extent the allegations are directed at Answering Defendants, Answering Defendants deny those allegations and demand strict proof thereof.

179. Paragraph 179 contains allegations that are not directed at Answering Defendants and therefore require no response from Answering Defendants. To the extent the allegations are directed at Answering Defendants, Answering Defendants deny those allegations and demand strict proof thereof.

180. Paragraph 180 contains allegations that are not directed at Answering Defendants and therefore require no response from Answering Defendants. To the extent the allegations are directed at Answering Defendants, Answering Defendants deny those allegations and demand strict proof thereof.

181. Paragraph 181 contains allegations that are not directed at Answering Defendants and therefore require no response from Answering Defendants. To the extent the allegations are directed at Answering Defendants, Answering Defendants deny those allegations and demand strict proof thereof.

182. Paragraph 182 contains allegations that are not directed at Answering Defendants and therefore require no response from Answering Defendants. To the extent the allegations are directed at Answering Defendants, Answering Defendants deny those allegations and demand strict proof thereof.

183. Paragraph 183 contains allegations that are not directed at Answering Defendants and therefore require no response from Answering Defendants. To the extent the allegations are directed at Answering Defendants, Answering Defendants deny those allegations and demand strict proof thereof.

184. Paragraph 184 contains allegations that are not directed at Answering Defendants and therefore require no response from Answering Defendants. To the extent the allegations are directed at Answering Defendants, Answering Defendants deny those allegations and demand strict proof thereof.

185. Paragraph 185 contains allegations that are not directed at Answering Defendants and therefore require no response from Answering Defendants. To the extent the allegations are directed at Answering Defendants, Answering Defendants deny those allegations and demand strict proof thereof.

With respect to the “WHEREFORE” paragraph immediately following paragraph 185, Answering Defendants admit that Plaintiffs seek the relief requested but deny that Plaintiffs are entitled to any such relief.

#### **GENERAL DENIAL**

To the extent any allegation in the Complaint is not specifically admitted, it is denied in its entirety.

#### **FIRST AFFIRMATIVE DEFENSE**

The Complaint fails to state a claim upon which relief can be granted.

#### **SECOND AFFIRMATIVE DEFENSE**

Plaintiffs’ causes of action are barred in whole or in part by the applicable statute of limitations, to the extent not otherwise provided in § IV.D.3.c, § IV.D.4.c, and/or § VII.B.4 of the Nationwide Settlement Agreement With American Home Products Corporation (“Settlement

Agreement”) approved by the United States District Court for the Eastern District of Pennsylvania.

**THIRD AFFIRMATIVE DEFENSE**

Plaintiffs’ causes of action are barred in whole or in part by the doctrine of laches, waiver and estoppel, to the extent not otherwise provided in § IV.D.3.c, § IV.D.4.c, and/or § VII.B.4 of the Settlement Agreement.

**FOURTH AFFIRMATIVE DEFENSE**

Plaintiffs’ Complaint is defective in that Plaintiffs have failed to join indispensable parties.

**FIFTH AFFIRMATIVE DEFENSE**

Plaintiffs’ causes of action are barred in whole or in part by Plaintiffs’ comparative and/or contributory negligence.

**SIXTH AFFIRMATIVE DEFENSE**

Plaintiffs’ damages, if any, were caused, solely or partially, or proximately caused by, some third person or third party for whom Answering Defendants are not legally responsible.

**SEVENTH AFFIRMATIVE DEFENSE**

Plaintiffs’ alleged damages resulted from new and independent, unforeseeable, superseding and/or intervening causes unrelated to any conduct of, or product placed in the stream of commerce by, Answering Defendants.

**EIGHTH AFFIRMATIVE DEFENSE**

Plaintiffs’ alleged damages were the result of pre-existing conditions unrelated to any conduct of, or product placed in the stream of commerce by, Answering Defendants.



**NINTH AFFIRMATIVE DEFENSE**

Plaintiffs' alleged damages were the result of an idiosyncratic reaction, which Answering Defendants could not reasonably foresee.

**TENTH AFFIRMATIVE DEFENSE**

Plaintiffs' damages, if any, and if they were caused by Pondimin or Redux, were caused in whole or in part by misuse or unintended use of the product.

**ELEVENTH AFFIRMATIVE DEFENSE**

Plaintiffs' damages, if any, were caused by changes and/or alterations to Answering Defendants' products made by persons not within Answering Defendants' control.

**TWELFTH AFFIRMATIVE DEFENSE**

Answering Defendants provided complete and adequate warnings to Plaintiffs' prescribing physicians. Therefore, any claims by Plaintiffs for inadequate warnings are controlled by, and barred under, the learned intermediary doctrine.

**THIRTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' causes of action are barred in whole or in part by the lack of a defect, as the pharmaceuticals ingested by Plaintiffs were properly prepared in accordance with the applicable standard of care.

**FOURTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' product liability causes of action are barred because the benefits of Pondimin and/or Redux outweighed the risks.

**FIFTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' product liability causes of action are barred because the relevant products were consistent with or exceeded consumer expectations.

**SIXTEENTH AFFIRMATIVE DEFENSE**

Based on the state of scientific, medical, and technological knowledge at the time Pondimin and/or Redux was marketed, the subject pharmaceuticals were reasonably safe for normal and foreseeable use at all relevant times.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred, in whole or in part, because Answering Defendants complied with all applicable state and federal statutes and with the requirements and regulations of the FDA.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims under Massachusetts law are barred by the doctrine of federal preemption.

**NINETEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims against Answering Defendants are barred under Section 402A, comment k of the Restatement (Second) of Torts and Section 6 et seq. of the Restatement (Third) of Torts: Products Liability.

**TWENTIETH AFFIRMATIVE DEFENSE**

Plaintiffs' strict liability claims cannot be maintained against a prescription drug manufacturer.

**TWENTY-FIRST AFFIRMATIVE DEFENSE**

The damages recoverable by Plaintiffs, if any, must be reduced by any amount of damages legally caused by Plaintiffs' failure to mitigate such damages in whole or in part.

**TWENTY-SECOND AFFIRMATIVE DEFENSE**

Answering Defendants expressly deny that any third party engaging in the acts alleged by Plaintiffs were acting as an agent or servant, or at the instruction or within the control of,

Answering Defendants. Therefore, to the extent that Plaintiffs seek to recover for the acts or omissions of such third parties, Plaintiffs' claims are barred as a matter of law.

**TWENTY-THIRD AFFIRMATIVE DEFENSE**

Each item of economic loss alleged in the Complaint was, or with reasonable certainty will be, replaced or indemnified, in whole or in part, from collateral sources.

**TWENTY-FOURTH AFFIRMATIVE DEFENSE**

Should Answering Defendants be held liable to Plaintiffs, which liability is specifically denied, Answering Defendants would be entitled to a set-off for all sums of money received or available from or on behalf of any tortfeasors for the same injuries alleged in the Complaint.

**TWENTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiffs have not suffered any physical injuries that were proximately caused by any act or omission by Answering Defendants, and it is more likely than not that Plaintiffs will not contract any illness or injury from the alleged use of the products which are the subject of this action.

**TWENTY-SIXTH AFFIRMATIVE DEFENSE**

All acts or omissions by Answering Defendants were undertaken in good faith without malice or recklessness, and were fully justified and reasonable under the circumstances.

**TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

Plaintiffs have failed to plead the claim of fraud with the requisite specificity required by law.

**TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

To the extent, if any, that punitive damages are not barred by the Settlement Agreement and are permitted under Massachusetts law, Plaintiffs' punitive damages claims are barred by the Constitution of the United States and the Constitution of the State of Massachusetts.

**TWENTY-NINTH AFFIRMATIVE DEFENSE**

To the extent, if any, that punitive damages are not barred by the Settlement Agreement and are permitted under Massachusetts law, Plaintiffs must prove a claim for punitive damages by proffering clear and convincing evidence of willful and malicious or wanton, reckless conduct, or by proffering evidence of a willing or knowing violation by Answering Defendants of the Massachusetts Consumer Act, Mass. Gen. Laws ch. 93A, §9, under Massachusetts and/or federal law. No act or omission by Answering Defendants was malicious, willful, wanton, reckless, or grossly negligent or in willful or knowing violation of the Consumer Act; therefore any award of punitive damages is barred.

**THIRTIETH AFFIRMATIVE DEFENSE**

To the extent, if any, that punitive damages are not barred by the Settlement Agreement and are permitted under Massachusetts law, punitive damages are unjust, discriminatory, unconstitutionally vague and/or overly broad, because there is no explicit standard by which they can be measured or determined.

**THIRTY-FIRST AFFIRMATIVE DEFENSE**

To the extent, if any, that punitive damages are not barred by the Settlement Agreement and are permitted under Massachusetts law, with respect to Plaintiffs' demand for punitive damages, Answering Defendants specifically incorporates by reference all standards or limitations regarding the determination and enforceability of punitive damages awards which arose in the U.S. Supreme Court decisions of *BMW of North America v. Gore*, 116 U.S. 1589 (1996) and *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408, 123 S.Ct. 1513 (2003).

**THIRTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiffs' claims are subject to dismissal or transfer on the basis of improper venue.

**THIRTY-THIRD AFFIRMATIVE DEFENSE**

Plaintiffs' eligibility to exercise an Intermediate Opt-Out right and file an individual lawsuit against Answering Defendants is subject to challenge by Answering Defendants pursuant to Section IV.D.3.c of the Settlement Agreement. Answering Defendants reserve the right to challenge Plaintiffs' eligibility if and when Answering Defendants discover that Plaintiffs are not eligible to exercise such an Intermediate Opt-Out right.

**THIRTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiffs' causes of action are barred because, at all relevant times, plaintiffs were knowledgeable purchasers who were aware of the alleged hazards of Redux and/or Pondimin and, therefore, Plaintiffs expressly or impliedly assumed the risk of any alleged damages.

**THIRTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiffs' causes of action are barred because a reasonable purchaser and/or consumer would have been aware of the alleged risks of Redux and/or Pondimin.

**THIRTY-SIXTH AFFIRMATIVE DEFENSE**

Plaintiffs' recovery, if any, should be reduced by the comparative negligence, fault, responsibility or causation attributable to third parties, for whom Answering Defendants are not legally responsible.

**THIRTY-SEVENTH AFFIRMATIVE DEFENSE**

Plaintiffs' causes of action are barred because Plaintiffs were not foreseeable users of the product.

**THIRTY-EIGHTH AFFIRMATIVE DEFENSE**

Plaintiffs' causes of action are barred because Plaintiffs' alleged damages were not caused by any failure to warn on the part of Answering Defendants.

**THIRTY-NINTH AFFIRMATIVE DEFENSE**

Plaintiffs' causes of action are barred in whole or in part by Plaintiffs' failure to assert a safer design for Redux and/or Pondimin.

**FORTIETH AFFIRMATIVE DEFENSE**

Plaintiffs' causes of action are barred in whole or in part because Answering Defendants complied with all applicable statutes and with the requirements and regulations of the FDA.

**FORTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiffs' causes of action are barred because they did not reasonably rely on any alleged express or implied warranty.

**FORTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiffs failed to notify Answering Defendants of any alleged breach of warranty within a reasonable time after they discovered or should have discovered any such alleged breach and are, therefore, barred from recovery for such claims.

**FORTY-THIRD AFFIRMATIVE DEFENSE**

Plaintiffs' causes of action are barred because Plaintiffs suffered no physical injury from Redux and/or Pondimin.

**FORTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiffs impermissibly seek to impose liability on conduct protected from liability by the First Amendment to the United States Constitution.

**FORTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims for punitive damages are in contravention of Answering Defendants' rights under the Commerce Clause of Article I, Section 8 of the United States Constitution, the Contracts Clause of Article I, Section 10 of the United States Constitution, and the prohibition against ex post facto laws embodied in Article I, Section 10 of the United States Constitution,

**FORTY-SIXTH AFFIRMATIVE DEFENSE**

Plaintiffs are not entitled to recovery attorney's fees.

**FORTY-SEVENTH AFFIRMATIVE DEFENSE**

Answering Defendants reserve the right to amend its Affirmative Defenses.

WHEREFORE, Answering Defendants demand judgment against Plaintiffs, as well as costs and such further relief as the Court deems just and proper.

**DEMAND FOR TRIAL BY JURY**

Answering Defendants demand a trial by jury on all issues so triable in this case.

Respectfully submitted this 1<sup>st</sup> day of June, 2004.

/s/ Janice W. Howe  
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Janice W. Howe BBO #242190  
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*Counsel for Defendants Wyeth and  
Wyeth Pharmaceuticals, Inc.*



**CERTIFICATE OF SERVICE**

This is to certify that I have this day served Wyeth Defendants' Answer to Plaintiffs' Amended Complaint upon all parties to the above-captioned action by hand, by United States First Class Mail, postage prepaid, or by Federal Express to all attorneys of record, this 1st day of June, 2004.

/s/ Janice W. Howe

Janice W. Howe

*Counsel for Defendants Wyeth  
and Wyeth Pharmaceuticals, Inc.*